

NOVARTIS AG  
Form 6-K  
November 07, 2011

# **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

## **FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 or 15d-16 OF  
THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated November 05, 2011**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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**Form 20-F: x**      Form 40-F: o

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Yes: o      **No: x**

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o      **No: x**

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**Novartis International AG**

Novartis Global Communications

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**- Investor Relations Release -**

**Novartis DEB025 data showed viral clearance as early as six weeks and potential for interferon-free therapy in hepatitis C patients**

- *Phase II data showed oral once daily DEB025 plus ribavirin provided viral clearance in almost half of genotype 2 and 3 patients with hepatitis C(1)*
- *DEB025 targets host proteins required for hepatitis C virus replication, showing activity across genotypes and high barrier to resistance(2)*
- *More than 170 million people worldwide(3) suffer from hepatitis C, a serious liver disease that can lead to cirrhosis, liver cancer and in some cases death*

**Basel, November 5, 2011** Novartis announced today new Phase II data showing that first-in-class DEB025 (alisporivir) may produce early viral elimination (or clearance) in interferon-free regimens (as monotherapy or with ribavirin), in previously untreated patients infected with the hepatitis C virus (HCV) genotypes 2 and 3(1).

These 12-week results were presented at the Association for the Study of the Liver (AASLD) Congress in San Francisco, United States. Also presented were new data on the compound's unique mode of action and high barrier to resistance in previously untreated patients infected with the HCV genotype 1(2).

Almost half the patients (49%) in the study on DEB025 plus ribavirin achieved viral clearance (negative HCV RNA) as early as week six(1). One third of patients (32%) receiving DEB025 alone also achieved viral clearance after six weeks(1). In addition, 97% of patients with viral clearance who continued to receive interferon-free DEB025 plus ribavirin maintained this viral clearance up to week 12(1). Achieving an early viral clearance is considered one of the most important predictors of sustained viral response, also known as viral cure. After genotype 1, genotypes 2 and 3 are the second most prevalent forms of HCV worldwide(4).

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Hepatitis C is difficult to treat and newly licensed direct-acting antivirals are not indicated for genotypes 2 and 3 patients(5), and may leave these patients without new treatment options and with no improvement in tolerability over interferon plus ribavirin, the standard of care , said Professor Jean-Michel Pawlotsky, Department Head of Virology at the Hôpital Henri Mondor, Créteil, France, and the study s principal investigator. These positive results suggest that DEB025 may be a valuable future treatment option either alone or in combination regimens, providing physicians with flexibility in the treatment process along with favorable tolerability and a high barrier to resistance.

DEB025 is the first in a new class of drugs called cyclophilin inhibitors. Unlike other compounds in development that target the virus directly, DEB025 is a host targeting antiviral that targets host proteins essential for the replication of all types of HCV. As a result, DEB025 may offer an effective treatment option across HCV genotypes, with a high barrier to resistance.

Hepatitis C remains a major public health problem with significant challenges of treatment resistance and poor tolerability, said John Hohneker, Global Head of Development for Integrated Hospital Care at Novartis. Novartis is committed to providing healthcare professionals with innovative and effective treatments that can help them tackle this global epidemic.

More than 170 million people worldwide are infected with HCV, representing nearly 3% of the world's population(3). The hepatitis C virus causes serious liver disease, leading to cirrhosis, liver cancer and, in some cases, death.

A pivotal Phase III study with DEB025 is ongoing to evaluate the efficacy and safety of DEB025 plus interferon and ribavirin in previously untreated HCV genotype 1 patients. Other Phase II trials are ongoing in other patient populations, i.e., genotype 1 experienced patients.

Novartis licensed DEB025 from Debiopharm GroupTM, an independent biopharmaceuticals company based in Switzerland, under an agreement that gives Novartis exclusive worldwide development, manufacturing and marketing rights (excluding Japan).

#### **About the study**

The study presented at AASLD was an international multicentre, randomized, parallel-group, open-label, multi-dose, exploratory 12-week interim analysis of 334 previously untreated chronic hepatitis C patients with genotypes 2 and 3. It evaluated the efficacy and safety of DEB025 either alone or in combination with ribavirin in terms of negative HCV RNA. In addition, the study examined the effect of add-on interferon treatment. There was a low incidence of serious adverse events, with rates of adverse events comparable between treatment groups(1). A low number of patients experienced a transient increase in bilirubin more than five times the upper limit of normal and all without any signs of liver toxicity(1). Interferon-free regimens displayed lower rates of flu like symptoms in comparison to the interferon arms(1).

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, can, suggest, may, future, committed, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for DEB025 or regarding potential future revenues from DEB025. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with DEB025 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that DEB025 will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that DEB025 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding DEB025 could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a

result of new information, future events or otherwise.

## About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>.

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## References

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Novartis AG**

Date: November 05, 2011

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
Title: Head Group Financial  
Reporting and Accounting